IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FORT SMITH DIVISION

UNITED STATES OF AMERICA. Plaintiff, v. 24 CASES (SIXTEEN, 18.7 OZ. BOXES PER CASE) MORE OR LESS, OF RAISIN BRAN CEREAL, AN ARTICLE OF FOOD, *et al*. Defendants *in rem.* And J AND L GROCERY, LLC, a corporation, and JAMES T. WHITE and LORI A. LAYNE, individuals, Defendants.	Civil No. 18-2188 PKH **AMENDED COMPLAINT**

Plaintiff, United States of America, by its attorney, Duane (Dak) Kees, United States Attorney for the Western District of Arkansas, brings this verified complaint and alleges as follows:

I. FORFEITURE

NATURE OF THE ACTION

1. This Complaint for Forfeiture was filed by the United States of America, and requested seizure and condemnation of articles of food, drug, device, and cosmetic as described in the caption ("Defendants *in rem*"), in accordance with the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq*.

A. Jurisdiction and Venue

2. This civil forfeiture action *in rem* was brought pursuant to 21 U.S.C. § 334 to seize and condemn the defendant articles because they are in violation of the Act. This Court has jurisdiction over such an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334.

3. This Court has *in rem* jurisdiction over the Defendants *in rem*, and venue is proper under 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1), because the Defendants *in rem* are located at 4810 N. Highway 71, Alma, Arkansas, in the Western District of Arkansas, Fort Smith Division.

B. The Defendants *in rem*

4. The Defendants *in rem* are articles of food, drug, device, and cosmetic within the meaning of 21 U.S.C. § 321(f)-(i) that located on the premises of J and L Grocery, LLC ("J&L"), 4810 N. Highway 71, Alma, Arkansas.

5. The Defendants *in rem* consist in whole or in part of components that were shipped in interstate commerce from outside the state of Arkansas.

6. The defendant articles of food are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

7. The defendant articles of drug are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(A), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered

injurious to health, and within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety, and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

8. The defendant articles of device are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(A), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health.

9. The defendant articles of cosmetic are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 361(c), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

10. Based on the foregoing, the Defendants *in rem* are held illegally within the jurisdiction of this Court and are liable to seizure, forfeiture, and condemnation pursuant to 21 U.S.C. § 334.

11. Upon filing of the complaint in this action, the United States requested that this Court issue an arrest warrant *in rem* pursuant to Supplemental Rule G(3)(b). The warrant *in rem* was duly issued by this Court and the United States executed the warrant upon the Defendants *in rem* on November 7, 2018.

II. INJUNCTIVE RELIEF

12. This Amended Complaint is further brought under the Act, 21 U.S.C. § 332(a), and this Court's inherent equitable authority, to permanently enjoin and restrain Defendants J and L Grocery, LLC, a corporation, and James T. White and Lori A. Layne, individuals (collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(k) by causing articles of food, as defined 21 U.S.C. § 321(f), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

B. 21 U.S.C. § 331(k) by causing articles of drug, as defined 21 U.S.C. § 321(g), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 351(a)(2)(A), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

C. 21 U.S.C. § 331(k) by causing articles of drug, as defined 21 U.S.C. § 321(g), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety, and

have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

D. 21 U.S.C. § 331(k) by causing articles of device, as defined 21 U.S.C. § 321(h), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 351(a)(2)(A), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health.

E. 21 U.S.C. § 331(k) by causing articles of cosmetic, as defined 21 U.S.C. § 321(i), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to be adulterated within the meaning of the Act, 21 U.S.C. § 361(c), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health.

A. Jurisdiction and Venue

13. This Court has jurisdiction to restrain violations of the Act under 21 U.S.C. § 332(a), and this Court also has jurisdiction over Defendants to this action under 28 U.S.C. §§ 1331, 1337, and 1345.

14. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

B. The Defendants

15. Defendant J and L Grocery, LLC, is incorporated in the State of Arkansas and does business at 4810 N. Highway 71, Alma, Arkansas ("J&L's Facility").

16. Defendant James T. White, is the owner of J&L and is its most responsible individual. He oversees all functions of the business, including purchasing and distributing

products. Defendant White helps manage J&L with Defendant Layne. Defendant White directs employees, interacts with customers, and works with contractors. Defendant White additionally handles the majority of the maintenance and receiving of product at J&L. Defendant White performs his duties at J&L's Facility, within the jurisdiction of this Court, and has ultimate responsibility to prevent, detect, and correct violations of the Act.

17. Defendant Lori A. Layne's title is Manager at J&L, and she is the most responsible individual at J&L when Mr. White is not at J&L's Facility. Defendant Layne manages the daily operations at J&L, directs employees, interacts with customers, and works with contractors. Defendant Layne performs her duties at J&L's Facility.

18. Defendants' business is part wholesale and part retail. Approximately half of their products are sold outside the State of Arkansas, including sales to Missouri, Oklahoma, and Kansas. Defendants often use suppliers, including suppliers located outside the State of Arkansas, to obtain food, drugs, devices, and cosmetics to sell and distribute from J&L, including suppliers in Texas and Illinois.

19. The adulteration of any food, drug, device, or cosmetic, while such article is held for sale after shipment of one or more of its components in interstate commerce, violates the Act. 21 U.S.C. § 331(k).

20. Defendants violate 21 U.S.C. § 331(k) by causing articles of food, drug, device, and cosmetic to become adulterated under 21 U.S.C. §§ 342(a)(4), 351(a)(2)(A), 351(a)(2)(B), and/or 361(c), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

FACTS

21. J&L receives, holds for sale, and distributes foods, drugs, devices, and cosmetics.

22. J&L's Facility consists of multiple buildings, including a main warehouse; a pricing shed; a retail store; a liquidation shed; six holding warehouses, numbered one (1) through six (6); a walk-in cooler; a walk-in freezer; and outdoor storage areas (outdoor storage areas on J&L's facility include three awning coverings, which are identified as follows: "Overhead covered Awning storage area adjacent to the Dock," "Overhead covered Awning storage area adjacent to the Freezer," and "Overhead covered Awning storage area adjacent to the Liquidation Warehouse").

23. The Arkansas Department of Health ("ADH") inspected J&L's Facility on July 26, 2017, pursuant to a contract with FDA. The ADH inspector's report stated that J&L failed to: remove litter and waste and to cut weeds and grass within the immediate vicinity of the facility's plant and structures that may constitute an attractant, breeding place or harborage area for pests; operate waste treatment and disposal systems in a manner that prevents contamination; provide adequate screening or other protection of its buildings against pests; maintain buildings, fixtures and other physical facilities in a sanitary condition; and store finished food under conditions that would protect against deterioration of the food in the container. The ADH inspector also stated that he "observed the entire warehouse facility and outside in need of cleaning and proper sanitation. During previous inspections, violations have been brought to management's attention, but have not been corrected."

24. FDA inspected J&L between July 16 and August 7, 2018. During the inspection, an FDA investigator observed widespread insanitary conditions throughout J&L's Facility. The FDA investigator's observations included but were not limited to:

A. Inadequate sanitation practices at J&L, including litter and pest activity (such as dead rodents, rodent excreta pellets, evidence of rodent gnawing on packaging, dead

insects, one or more stray cats, animal feces, and rodent urine stains). The investigator observed food pallets with rodent excreta pellets on them, evidence of rodent gnawing, and rodent urine stains. The investigator also noted that, at the time of the inspection, J&L had not contracted for pest control services for warehouses 1-6.

B. Inadequate pest control and J&L's failure to construct its facilities to facilitate maintenance and sanitary operations. There was widespread evidence of J&L's failure to exclude pests from its facilities, including rodent excreta pellets, evidence of rodent gnawing, and rodent urine stains, and possible points of pest ingress routes in the form of gaps in the walls and/or open doors of multiple structures. Indeed, the FDA investigator observed live and dead rodents and dead insects and a strong urine-like odor within parts of J&L's Facility. In addition to the structural problems, the pallets within J&L's warehouses were not adequately spaced to allow for inspection within warehouses 1-6, nor did they provide adequate lighting.

C. Inadequate groundskeeping to protect against the contamination of food. The investigator observed overgrown grass and brush, piles of debris, all of which may constitute an attractant, breeding place, or harborage for pests.

25. At the close of the inspection, Mr. White and Ms. Layne spoke with the FDA investigator about these conditions. They stated that they would start contracting for pest control services for warehouses 1 through 6 and that they had started cleaning up J&L's Facility.

26. FDA conducted a follow-up inspection at J&L between September 19 and October 23, 2018. During the inspection, FDA investigators again observed articles of food, drug, device, and cosmetics at J&L's facility being held under insanitary conditions. The insanitary conditions observed by FDA investigators included but were not limited to:

A. Widespread pest infestation throughout the main warehouse, warehouses 1-6, the liquidation shed, and the pricing shed, including multiple live and dead rodents; rodent excreta pellets too numerous to count in, on, and around containers of food, drug, device, and cosmetic products; animal feces; numerous containers that had been rodent gnawed; food, drug, device, and cosmetic product packaging with stains characteristic of rodent urine; rodent nesting material between food pallets; live and dead insects in contact with food, drug, device, and cosmetic products; and live raccoons and at least one live cat in the storage areas.

B. Building defects, such as holes through exterior walls and gaps under doors, and water damage, which serve as access points into the buildings for pests. The investigator heard pest sounds in the walls and ceilings of the main warehouse.

C. Insufficient maintenance of the grounds, including overgrown brush, downed tree limbs, litter in front of the buildings, and piles of debris outside of the buildings.

D. Water leaks in the roof inside the liquidation shed.

E. Lack of protection against product contamination, including open boxes of comingled products with apparent pest activity therein.

27. During the September/October 2018 inspection, FDA investigators also observed evidence of expired drug and device products being held for sale in multiple storage locations for wholesale and retail customers. FDA investigators further observed products being stored and held for sale in outdoor storage locations that failed to provide protection from the outside environment or from pest and rodent infestation, and that did not provide an environment where temperature and humidity could be controlled (including the Overhead covered Awning storage area adjacent to the Dock, Overhead covered Awning storage area adjacent to the Freezer, and Overhead covered Awning storage area adjacent to the Liquidation Warehouse). Investigators

noted that drug products were not stored at recommended temperatures to prevent adversely affecting their identity, strength, quality, and purity during storage, and that drug products that had been subject to improper storage conditions were salvaged and returned to the marketplace without appropriate testing and inspection, as required by 21 C.F.R. § 211.208.

28. Photographs of some of the conditions FDA investigators observed during the September/October 2018 inspection are attached as Exhibit A to the this Amended Complaint.

29. FDA's laboratory analyses of samples collected during the September/October 2018 inspection confirmed the presence of filth, including rodent urine, rodent excreta pellets, rodent hairs, and rodent gnaw holes in product packaging.

30. Based on the foregoing, Defendants violate 21 U.S.C. § 331(k) by causing articles of food, drug, device, and cosmetic to become adulterated under 21 U.S.C. §§ 342(a)(4), 351(a)(2)(A), 351(a)(2)(B), and/or 361(c), while such articles are held for sale after shipment of one or more of their components in interstate commerce. Unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

III. REQUESTED RELIEF

A. Forfeiture

WHEREFORE, FDA requests that this Court decree forfeiture of Defendants *in rem* to the United States; that the Defendants *in rem* be disposed of as this Court may direct pursuant to the provisions of the Act; and that Plaintiff be awarded its costs and disbursements in this action *in rem*, and for such other and further relief as the Court deems proper and just.

B. Injunctive Relief

WHEREFORE, FDA requests that this Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(k) by causing articles of food, as defined 21 U.S.C. § 321(f), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

B. Violating 21 U.S.C. § 331(k) by causing articles of drug, as defined 21 U.S.C. § 321(g), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 351(a)(2)(A), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

C. Violating 21 U.S.C. § 331(k) by causing articles of drug, as defined 21 U.S.C. § 321(g), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, § 351(a)(2)(B), in that the facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety, and

have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

D. Violating 21 U.S.C. § 331(k) by causing articles of device, as defined 21 U.S.C. § 321(h), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 351(a)(2)(A), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health.

E. Violating 21 U.S.C. § 331(k) by causing articles of cosmetic, as defined 21 U.S.C. § 321(i), while such articles are held for sale after shipment of one or more of their components in interstate commerce, to become adulterated within the meaning of the Act, 21 U.S.C. § 361(c), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health.

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from holding for sale any article of food, drug, device, and/or cosmetic, unless and until Defendants bring their operations into compliance with the Act and its implementing regulations to the satisfaction of FDA; and

III. Award the United States its costs herein, including costs of investigation to date, and such other relief as the Court may deem just and proper.

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